



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,763	09/29/2006	Kazuwa Nakao	1254-0327PUS1	6725
2292 7590 01/31/2012 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER HOWARD, ZACHARY C				
ART UNIT		PAPER NUMBER		
1646				
NOTIFICATION DATE		DELIVERY MODE		
01/31/2012		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/594,763

Applicant(s)

NAKAO ET AL.

Examiner

ZACHARY HOWARD

Art Unit

1646

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-13, 16 and 18-22 is/are pending in the application.
- 5a) Of the above claim(s) 1-10 and 18-21 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 11-13, 16 and 22 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 11-13, 16 and 22 are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 10/14/11 has been entered in full. Claims 11 and 22 are amended. Claims 1-13, 16, and 18-22 are pending in the instant application.

Claims 1-10 and 18-21 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in the reply filed on 6/8/09.

Claims 11-13, 16 and 22 are under consideration, in so far as they are drawn to the elected species.

Withdrawn Objections and/or Rejections

The objections to claims 11 and 22 at page 10 of the 4/15/11 Office Action are *withdrawn* in view of Applicants' amendments to the claims.

Maintained Objections and/or Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants are advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1646

Claims 11-13, 16 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyazawa et al (2002. Endocrinology. 143(9): 3604-3610; cited previously), and further in view of Suda et al, 1998 (Proc Natl Acad Sci USA; reference CA on the 11/25/09 IDS). This rejection was set forth previously at pg 2-10 of the 4/15/11 Office Action.

Applicants' arguments (10/14/11; pg 5-7) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response, Applicants first argue (pg 6) that peripheral CNP expression arises by local CNP production because CNP is not detected in the circulation; Applicants point to a teaching on page 3702 of Chrisman et al, 1993 in support. Applicants argue that "as seen from the teaching of Chrisman, CNP had not been detected within the circulation at the priority date of the present application" (pg 6).

This argument has been fully considered but is not found to be persuasive. It is acknowledged that Chrisman et al (1993) teach that CNP has not been detected in the circulation. However, subsequent to this publication in 1993, the relevant art showed that CNP is present in the circulation. Kierner et al (2002; 11/9/06 IDS) was cited in the previous Office Action by the Examiner as teaching that CNP expression is present in peripheral cells including endothelial cells and macrophages. Furthermore, it was well known in the art prior to the time of filing of the instant application that CNP was secreted by said endothelial cells into the plasma. See Buckley et al (2000), who teach the "mean plasma level of CNP in the 20 normal healthy subject was 0.62 ± 0.04 pmol/l" (pg 469 of Buckley et al, 2000. Clinical Science. 99: 467-472). On page 470, Buckley et al further cites a reference (17, Hama et al) published in 1994 showing CNP circulating in the plasma. Thus, at the time of filing of the instant application (3/31/05, with foreign priority claimed to 3/31/04), the person of ordinary skill in the art would not have understood CNP to be expressed exclusively in non-circulating tissues, but rather would have understood CNP to be circulating in the plasma. Furthermore, even if CNP were not naturally secreted in the plasma this argument would not be considered persuasive because the promoter used by Suda et al is a liver-specific promoter (human serum amyloid P component) that results in overexpression of plasma BNP.

Applicants further argue that it is not clear from the teachings of Suda et al whether the overgrowth in BNP transgenic mice is caused by activation of either or both of GC-A and GC-B receptors in the bone through increase in blood BNP concentration because Suda et al teach that their results do not rule out the possibility of an unidentified BNP-specific receptor in the bone. Applicants further argue that Suda et al assume circulation of BNP but does not provide evidence of such.

This argument has been fully considered but is not found to be persuasive. Suda et al specifically teach determination of plasma BNP concentrations (see page 2337, right column. Page 2338, paragraph bridging left and right columns); thus, the argument that Suda et al only assume circulation of BNP is not persuasive because Suda et al provides evidence of such. Furthermore, while it is acknowledged that Suda et al teach that their results do not rule out the possibility of a BNP receptor other than GC-B in the bone, this does not conflict with their strong results suggesting that BNP is activating GC-B. As set forth previously, Suda et al teach that their findings "suggest strongly that activation of chondrogenesis by natriuretic peptides is mediate primarily by GC-B" and "that CNP, a selective activator of GC-B, increases the total longitudinal bone growth and cGMP production in cultured embryonic mouse tibias more potently than BNP, an activator of GC-A". While BNP could also activate an unidentified receptor in the bone, in view of the fact that CNP (which is selective for GC-B) also increases bone growth *in vitro*, the skilled artisan would reasonably expect that systemic CNP would have an effect to similar to systemic BNP on bone growth. As set forth previously, the skilled artisan would have had a reasonable expectation of success in expressing CNP systemically because of the success of Suda et al in expressing BNP systemically.

Thus, as Applicants' arguments are not found to be persuasive, the rejection is maintained for the reasons of record.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./

Examiner, Art Unit 1646

/Bridget E Bunner/

Primary Examiner, Art Unit 1647